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| 09/674,370 | 10/30/2000 | Kristina Schmidt | F6689 | 6987 | |
| 7590 08/20/2003 | | | • | • | |
| Jordan and Hamburg | | | EXAMINER | | |
| 122 East 42nd Street New York, NY 10168 | | | QUAN, ELIZ | QUAN, ELIZABETH S | |
| | | • | ART UNIT | PAPER NUMBER | |
| • | | | 1743 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

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|---|--|---|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| | 09/674,370 | SCHMIDT ET AL. | | | | |
| Office Action Summary | Examin r | Art Unit | | | | |
| | Elizabeth Quan | 1743 | | | | |
| Th MAILING DATE of this communication appears on the cover sheet with the correspondence address Peri d for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONED | ely filed will be considered timely. the mailing date of this communication. 0 (35 U.S.C. § 133). | | | | |
| 1) Responsive to communication(s) filed on 23 N | fav 2003 . | | | | | |
| | s action is non-final. | | | | | |
| , <u>, </u> | ,— | | | | | |
| closed in accordance with the practice under <i>I</i> Disposition of Claims | | | | | | |
| 4) Claim(s) 1,3-12 and 15-19 is/are pending in the | e application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1,3-12 and 15-19</u> is/are rejected. | | | | | | |
| 7)⊠ Claim(s) <u>1 and 15-17</u> is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☑ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provides 15)☐ Acknowledgment is made of a claim for domestic | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) 🔲 Notice of Informal P | (PTO-413) Paper No(s) atent Application (PTO-152) | | | | |
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DETAILED ACTION

Specification

- 1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
- 2. The disclosure is objected to because of the following informalities: There are spelling errors in the substitute specification.

Appropriate correction is required.

Claim Objections

- 3. Claim 1 is objected to because of the following informalities: capillarily should be capillary. Appropriate correction is required.
- 4. Claims 15-17 are objected to because of the following informalities: they are dependent on cancelled claims 13 and 14. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-12, 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Referring to claims 1, 3, and 12, t is unclear how the liquid supply supplies liquid to the capillary gaps. According to

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the specification, hoses are associated with each capillary gap. It is unclear how the hoses are attached to the capillary gap. FIG. 1a of the drawings show hoses attached to the capillary gap; however, it is unclear how that would work with an elongated capillary cap as show in FIGS. 1 and 2.

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
- 2. Claims 1, 3-12, and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how the at least one liquid supply is connected to the capillary gaps.
- 4. Claim 6 recites the limitation "the support plate" in the second line. There is insufficient antecedent basis for this limitation in the claim.
- Referring to claims 4 and 5, what does "plane cover plate" and "plane support plate"

 Are
 mean? Is the cover plate and support plate planar?
- 6. Referring to claims 6 and 7, it is confusing when the body and opposite body change names to support plate and cover plate, respectively, later on in the claims.

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7. Referring to claim 15, it is unclear what the structural difference between plane and planar is. Are there three groups to select from--plane substrate plate, planar substrate plate, and substrate plate with recesses?

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,279,791 to Aldrich et al.

Referring to claims 1, 10, and 12, Aldrich et al. disclose a device for transporting liquids along predetermined guide ways comprising a body (30) and opposite body (20) (see FIG. 5; ABSTRACT). The opposite body (20) is attachable to the body (30) in juxtaposition thereto (see FIG. 5). The opposite body (20) has a shape complementary to a corresponding shape of the body (30) (see FIG. 5). The body (30) is provided with one elevation and at least one recess on a side thereof, which faces a confronting surface of the opposite body (20) when attached thereto (see FIG. 5). The elevation is generally bar-shaped structure (see FIG. 5). The surfaces of the one elevation and at least one recess facing the confronting surface is spaced apart therefrom a distance such that the one elevation and at least one recess respectively define in conjunction with the confronting surface a capillary gap (50) for transporting liquids by capillary forces and at least one recessed region (60) there between, which are capillary inactive (see FIG. 5; COL. 5, lines 31-58). The recessed region (60) has a gap dimension of 1.0 mm or 1000 micrometers (see COL. 5, lines 34-37). Transport of liquids between adjacent capillary gaps is prevented (see COL. 5, lines 31-58). Each capillary gap (50) has an inlet and outlet each (see FIG. 5).

Aldrich et al. do not explicitly disclose a plurality of elevations and recesses. However, Aldrich et al. disclose that the shape of the body and opposite body is not material (see COL. 4, lines 1-15). In fact, there are many variations in physical shapes that can exist (see COL. 4, lines 1-15). Therefore, it would have been obvious to one

having ordinary skill in the art at the time the invention was made to modify the shape or duplicate essential working parts to have a plurality of elevation and recesses since it was held that change in form or shape is an obvious engineering design (*In re Dailey*, 149 USPQ 47 (CCPA 1976)) and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (*St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8), respectively. Additionally, in *Sjolund v. Musland*, 6 USPQ 2d 2020 (Fed. Cir. 1988), the prior art showed use of a certain single net panel while the claim called for two or more panels. Arguably, no obviousness was found because no explicit suggestion was provided as to the modification of the single net panel into multiple net panels. See also *In re Bode*, 193 USPQ 12, 16 (CCPA 1977); *In re Thompson*, 193 USPQ 275, 277 (CCPA 1976); *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976).

Aldrich et al. do not explicitly disclose the recessed regions having a width of at least 1000 micrometers and depth of at least 1500 micrometers. However, Aldrich et al. disclose that the actual size necessary to support capillary flow will vary with the liquid, nature of the surface contacted by the liquid, and contact angle between the liquid and the surface (see COL. 6, lines 6-9). Aldrich et al. disclose that cited dimensions are generally valid for aqueous liquids and plastic surfaces, but the actual gaps necessary to achieve capillary flow for a particular liquid/surface-material pair should be verified empirically (see COL. 6, lines 9-14). Aldrich et al. further disclose that significant variation from the numerical values can occur, but the principle of a capillary gap at the edge between the interior and exterior of the cartridge with a larger contiguous interior space still applies

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(see COL. 6, lines 14-18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the size of the recess regions to support capillary flow when considering the use of different liquids, surfaces contacted by the liquid, and contact angles between the liquid and surface.

5. Claims 1, 3-5, 10, 11, 15, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,051,190 to Birch et al.

Referring to claims 1, 3-5, 10, 11, 15, 17, Birch et al. disclose a device for transporting liquids along predetermined guide ways comprising a body (20) and opposite body (22) (see FIGS. 1-3, 7, and 8). The opposite body (22) is attachable to the body (20) in juxtaposition thereto (see FIG. 3). The opposite body (22) has a shape complementary to a corresponding shape of the body (20) (see FIG. 3). The opposite body (22), which is planar, is provided with recesses (see FIG. 3). The body (20) is provided with elevations and recesses on a side thereof, which faces a confronting surface of the opposite body (22) when attached thereto (see FIG. 3). The elevations are generally bar-shaped structures (see FIGS. 2 and 3). The surfaces of the elevations and recesses facing the confronting surface is spaced apart therefrom a distance such that the elevations and recesses respectively define in conjunction with the confronting surface a capillary gap for transporting liquids by capillary forces and at least one recessed region there between, which are capillary inactive (see FIG. 3). Transport of liquids between adjacent capillary gaps is prevented (see COL. 5, lines 40-45; COL. 7, lines 21-25). There is at least one liquid supply for supplying liquid dosing to the capillary gaps (see FIG. 3; COL. 7, lines 29-37). The body (20), which is in the form of a plane cover plate,

is removably attachable to the opposite body (22), which is in the form of a planar substrate or support plate, in a manner substantially free of tensions in different directions (see FIG. 3; COL. 3, lines 18-20; COL. 7, lines 29-37). The opposite body (22) is in the form of a microtiter plate (see FIG. 3; COL. 7, lines 10-37).

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Birch et al. do not address the dimensions of the capillary inactive recessed regions. However, Birch et al. disclose that the elevations are arranged and separated so that they are aligned with a collection of wells distributed in a multi-well plate (see COL. 7, lines 10-15). It is well known that multi-well plates come in a variety of dimensions depending on the number of wells required or desired to complete an assay. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Birch et al. to provide recessed regions with a width of at least 1000 micrometers and depth of at least 1500 micrometers as necessary to conform to the spacing among wells of the selected multi-well plate. It is further noted that it has been held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984)). Additionally, it has also been held that that discovering the optimum value of a result effective variable involves only routine skill in the art (In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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6. Claims 6, 7, 8, 9, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,051,190 to Birch et al. as applied to claims 1, 3-5, 11, 15, 17 above, and further in view of U.S. Patent No. 6,143,496 to Brown et al.

Referring to claims 8, 9, 18, 19, Birch et al. do not explicitly disclose the use of spacers. However, Birch et al. disclose that the elevations are lowered to the point such that each drop is in contact with the interior of each of the corresponding well (24) (see COL. 7, lines 25-27). Approximately 50% of the drop will be deposited into the well at the pre-determined depth the elevation is immersed into a liquid-containing reservoir (see COL. 3, lines 17-19; COL. 7, lines 27-29). This value may vary with different depths the elevation is immersed into the reservoir (see COL. 6, lines 1-6). Brown et al. reinforce the importance of spacers in maintaining the space between the two bodies (see COL. 28, lines 26-34). Spacers help align and keep two bodies together (see COL. 28, lines 26-34). Brown et al. show the spacers in the form of bars spaced apart in a regular pattern (see FIGS. 1, 2, 4, and 5). It is noted that since the spacers keep the body and opposite body together they are components that can be considered as part of the body, opposite body, or both the body and opposite body. The pattern ensures that all portions of the two bodies are maintained at the pre-determined distance (see FIGS. 1, 2, 4, and 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Birch et al. to provide spacers as Brown et al. to align and keep the two bodies together and maintain the desired or required space between the bodies.

7. Claims 8, 9, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,279,791 to Aldrich et al. as applied to claims 1, 3-5, 11, 15, 17 above, and further in view of U.S. Patent No. 6,143,496 to Brown et al.

Referring to claims 8, 9, 18, 19, Aldrich et al. do not explicitly disclose the use of spacers. However, Brown et al. disclose the importance of spacers in maintaining the space between the two bodies (see COL. 28, lines 26-34). Spacers help align and keep two bodies together (see COL. 28, lines 26-34). Brown et al. show the spacers in the form of bars spaced apart in a regular pattern (see FIGS. 1, 2, 4, and 5). The pattern ensures that all portions of the two bodies are maintained at the pre-determined distance (see FIGS. 1, 2, 4, and 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Aldrich et al. to provide spacers as Brown et al. to align and keep the two bodies together and maintain the desired or required space between the bodies.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,051,190 to Birch et al. as applied to claims 1, 3-5, 11, 15, 17 above, and further in view of U.S. Patent No. 5,304,487 to Wilding et al.

Referring to claim 16, Birch et al. do not explicitly disclose that the opposite body is in the form of a biochip. However, it is very well known to use a chip as the opposite body since the chip can perform detection and analyses as disclosed by Wilding et al. Wilding et al. disclose the opposite body comprises a chip containing the mesoscale flow system that can perform a wide range of tests (see COL. 3, lines 23, 24, and 44-55; COL. 4, lines 23 and 24). Therefore, it would have been obvious to one having ordinary skill in

the art at the time the invention was made to modify the apparatus of Birch et al. to provide a chip as the opposite body as in Wilding et al. to perform tests, analyses, and detection right on the chip.

Response to Arguments

9. Applicant's arguments with respect to claims 1, 3-12, and 15-19 have been considered but are most in view of the new ground(s) of rejection.

Conclusion

- 10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims. They all also deal with capillary gaps and capillary breaks.
- Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan Examiner Art Unit 1743

eq August 7, 2003

> Supervisory Patent Examiner Technology Center 1700

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